## **REMARKS/ARGUMENTS**

The Office Action has been carefully considered. Before entry of this paper, the status of the application is as follows:

- Claims 1-11, 13, 15, 17, 19-20, 24-29, 31-52, 54, 56, 58, 60, 61, 65-70, 72-79, and 81-84 are pending in the application, of which claim 83 has been withdrawn from consideration.
- Claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin et al. (U.S. Pub. No. 2004/0138712; hereinafter "Tamarkin") and further in view of Castel (US 5,413,550; hereinafter "Castel").
- Claims 11, 15, 17, 31, 32, 35, 36, 38, 52, 56, 58, 72, 73, 76, 77, and 79 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin and further in view of Castel and Ella *et al.* (U.S. Pub. No. 2004/0260209; hereinafter "Ella").
- Claims 33, 34, 37, 74, 75, and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin, in view of Castel and Ella, and further in view of Hansjurgens *et al.* (US 5,573,552; hereinafter "Hansjurgens").
- Claims 39, 81, and 82 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin and Castel, and further in view of Cosman (U.S. Pat. No. 6,405,072; hereinafter "Cosman").
- Claims 41, 42, and 84 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin and Castel, and further in view of Lia *et al.* (U.S. Pub. No. 2004/0019286; hereinafter "Lia").

In this paper, claims 1, 36, 43, and 77 are amended. Support for these amendments can be found throughout Applicant's specification including the as-filed claims, for example, at lines 13-17 at page 6, and line 31 at page 21 through line 9 at page 22 of the as-filed application, and in claims 19, 37, 76, and 78 as originally presented.

Claims 19, 37, 60, 76, and 78 are cancelled.

No new matter has been introduced.

Amendment and/or cancellation of any of the claims herein are not to be construed as acquiescence to any of the objections/rejections set forth in the Office Action and were done solely to expedite prosecution of the application. Applicant reserves the right to pursue any non-elected, cancelled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional application(s).

In view of the amendments above and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections of all the pending claims.

## Claim Rejections – 35 U.S.C. § 103(a)

In the Office Action, claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin and further in view of Castel. The Office asserts that the present invention is obvious in view of the teaching of EP 1,219,278 on a treatment system using an ultrasound apparatus for transmitting ultrasound waves to the region of treatment, the teaching of Tamarkin on interferential stimulation, and the teaching of Castel on the intensity of the ultrasound waves (*see* page 3 of the Office Action). Applicant first points out that the rejection of claims 19 and 60 is now moot. Applicant disagrees and hereby traverses the rejection of the claims now pending.

Nevertheless, without conceding the validity of the rejection and solely for facilitating the prosecution of the present application, Applicant submits that the independent claims (i.e., claims 1 and 43) are amended in this paper. For example, claim 1 as amended now recites that both of the operational frequencies of the ultrasound apparatus and the electrical stimulation apparatus are varied over time during the same treatment session, and that the operational frequency of the ultrasound apparatus is varied at a rate that is inversely proportional to a rate at which the operational frequency of the electrical stimulation apparatus is varied (*see* claim 1 for details). Applicant submits that claims 1 and 43 and those depending therefrom are clearly patentable over EP 1,219,278 in view of Tamarkin and Castel.

Applicant contends that the combination of the above-mentioned references fails in teaching or suggesting each and every feature of the treatment system/method that is presently recited and claimed. In particular, Applicant notes that the combination of EP 1,219,278, Tamarkin, and Castel fails in teaching or suggesting, among many things, a feature that the operational frequency of the ultrasound apparatus (or waves) is varied at a rate that is inversely proportional to a rate at which the operational frequency of the electrical stimulation apparatus (or interferential stimulation) is varied during the same treatment session. More specifically, EP 1,219,278 does not even teach or suggest that the operational frequency of the ultrasound apparatus can be varied over time during a single treatment session, much less that the operational frequencies of the ultrasound apparatus and the electrical stimulation are varied at the rates inversely proportional to each other (as required by this invention). Further, Applicant notes

that EP 1,219,278 does not teach electrical stimulation of any form in its disclosure, let alone a simultaneous application of the electrical stimulation and ultrasound waves.

Applicant also submits that Tamarkin and Castel cannot and will not cure the deficiencies of EP 1,219,278. In this regard, it is noted that Tamarkin does not teach or suggest that the operational frequency of the electrical stimulation apparatus may be varied over time during a treatment session. Tamarkin does not expressly teach the simultaneous application of ultrasound waves and electrical stimulation to the treatment region. Indeed, Tamarkin does not teach a treatment system or method which involves the transmission of ultrasound waves at all, much less a system or method having the operational frequencies of the ultrasound apparatus and the electrical stimulation varied at the rates inversely proportional to each other during the same treatment session.

Applicant further contends that Castel also fails in disclosing a treatment system or method in which a simultaneous application of electrical stimulation and ultrasound waves. Indeed, Castel fails in teaching electrical stimulation of any form, let alone a specific form of the electrical stimulation (i.e., interferential stimulation). Clearly, Castel fails in teaching many important features of the invention including, that the operational frequency of the electrical stimulation is varied over time, and that operational frequencies of the ultrasound apparatus and the electrical stimulation are varied at the rates inversely proportional to each other in a single session (as required by this invention). Applicant notes that Castel merely teaches varying *intensity* over the treatment time, and that it does not teach at all varying the operational *frequency* of the ultrasound apparatus over time in *a single treatment session*. Accordingly, Applicant submits that the combination of EP 1,219,278, Tamarkin, and Castel fails to teach or suggest all the features of the presently claimed system/method, including at least the feature that the *operational frequencies* of the ultrasound apparatus and the electrical stimulation varied at the rates inversely proportional to each other *during the same treatment session*.

Furthermore, Applicant submits that none of EP 1,219,278, Tamarkin, and Castel provides the specific motivation or suggestion to an artisan of ordinary skill to combine and then modify their teachings to arrive at the claimed invention. Specifically, *nothing* in EP 1,219,278 suggests that an application of ultrasound waves at the specific intensity range would produce cavitation effects to an extent necessary for inducing fat dissolution and cracks in the collagen fibers on the treatment region (as intended in this invention). Further, Applicant notes that

Tamarkin is rather intended for achieving a very different purpose, that is, enhancing delivery of an active substance into the skin. Unlike the present invention which relies on cavitation effects in achieving its objectives, such cavitation effects would be deemed unnecessary in achieving a skin delivery enhancement as intended in Tamarkin. Moreover, as indicated clearly in its disclosure, Tamarkin mainly focuses on using iontophoretic and/or electrical simulations to achieve the desired skin delivery. It is apparent that ultrasound devices are <u>not</u> of any great interest in Tamarkin. Accordingly, Applicant submits that, when one skilled in the art is presented with the problem which the present inventor was facing, one would not consult with either EP 1,219,278 or Tamarkin for solving the problem, let alone would be motivated by them.

Applicant further contends that, when one skilled in the art is presented with the problem which the present inventor was facing, one would not turn to Castel for solving the problem either. It is noted that the ultrasound treatment of Castel is intended for very different purposes (e.g., pain relief, soft tissue injuries, wound healing, etc), rather than reducing body perimeter via the dissolution of cellulite (of this invention). In absence of any specific teachings or motivation, Applicant submits that a skilled artisan would not be motivated to make a combination of EP 1,219,278, Tamarkin, and Castel for the purpose of arriving at the present invention. Even assuming that one were to make such a combination, one would still fail in the attempt as the combination of EP 1,219,278, Tamarkin, and Castel does not teach or suggest each and every element of the claimed subject matter, for the reasons as above discussed.

In view of the foregoing discussions, Applicant submits that pending claims 1-10, 13, 20, 24-29, 40, 43-51, 54, 61, and 65-70 are patentable over EP 1,219,278 in view of Tamarkin and Castel. Therefore, the reconsideration and withdrawal of the instant rejection over EP 1,219,278 in view of Tamarkin and Castel is proper and the same is requested.

Claims 11, 15, 17, 31, 32, 35, 36, 38, 52, 56, 58, 72, 73, 76, 77, and 79 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over EP 1,219,278 in view of Tamarkin and further in view of Castel and Ella. Applicant respectfully traverses the rejection in view of the claim amendments as presented herein.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin and Castel is applicable in this section of discussion, as the

instant claims (by virtue of their dependency to claim 1 or 43) are patentable over EP 1,219,278 and Tamarkin in view of Castel.

Applicant submits that the addition of Ella would not render the presently claimed subject matters obvious. Nothing in Ella teaches or suggests that an important feature (among many others) of the present invention, that is, the *operational frequencies* of the ultrasound apparatus and the electrical stimulation varied at the rates inversely proportional to each other *during the same treatment session*. Thus, Applicant submits that the addition of Ella fails in making up for the deficiencies of EP 1,219,278, Tamarkin and Castel.

Applicant further notes that Ella does not present any specific motivation or suggestion that is needed for a skilled artisan to arrive at the presently claimed system/method. Applicant submits again that one would not turn to Ella for achieving the intended purposes of this invention (e.g., inducing fat dissolution and cracks in the collagen fibers of the treatment region), as the intensity level at which the Ella's apparatus is operated clearly falls short to induce sufficient cavitation effects that are required herein. Indeed, nothing in Ella would motivate a skilled artisan to make a combination of EP 1,219,278, Tamarkin, Castel, and Ella for the purpose of arriving at the claimed system/method. Even *assuming* that a skilled artisan were to make such a combination, he/she would still fail in the attempt as the combination of these references still fails in teaching or suggesting each and every element of the claimed subject matter (e.g., the operational frequencies of the ultrasound apparatus and the electrical stimulation varied at the rates inversely proportional to each other during the same treatment session).

As such, Applicant submits that claims 11, 15, 17, 31, 32, 35, 36, 38, 52, 56, 58, 72, 73, 76, 77, and 79 are patentable over EP 1,219,278 and Tamarkin in view of Castel and Ella. Thus, reconsideration and withdrawal of the instant rejection under 35 USC 103(a) is proper and the same is requested.

In the Office Action, claims 33, 34, 37, 74, 75, and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 and Tamarkin, in view of Castel and Ella, and further in view of Hansjurgens. In particular, the Examiner asserts that Hansjurgens teaches a system wherein the frequency is varied at a rate that is inversely proportional to the variation of intensity (*see* page 7 of the Office Action). The rejection of claims 37 and 78 is now

moot in view of the cancellation of these claims. Applicant respectfully disagrees and traverses the rejection of pending claims 33, 34, 74, and 75.

Applicant submits that the above-reasoning rebutting the rejection over EP 1,219,278 and Tamarkin in view of Castel and Ella is also applicable in this section of discussion and hereby is incorporated by its entirety.

Applicant contends that the addition of Hansjurgens still fails in rendering the presently claimed subject matters obvious. In particular, the present invention is now directed to a system or method, wherein *both of the operational frequencies* of the ultrasound apparatus and the electrical stimulation apparatus are varied over the time during an individual treatment session, while the <u>operational frequency</u> of the ultrasound apparatus is varied at a rate that is inversely proportional to a rate at which <u>the operational frequency</u> of the electrical stimulation apparatus is varied (*see*, e.g., claim 1 for details).

In contrast, Hansjurgens merely teaches that the variation rate of the <u>frequency</u> can be inversely proportional to the variation rate of the <u>intensity</u> of an electrical stimulation. Nothing in Hansjurgens teaches or suggests varying the operational <u>frequency</u> of the ultrasound apparatus inversely proportional to the operational <u>frequency</u> of the electrical stimulation apparatus (as required by this invention). In other words, unlike the present invention which requires a specific correlation between the **frequency** (of the ultrasound waves) **and the frequency** (of the electrical stimulation), Hansjurgens instead teaches a correlation between **the frequency and the intensity** of an electrical stimulation. Indeed, Applicant notes that Hansjurgens does not even teach an ultrasound apparatus at all. Accordingly, Applicant submits that the addition of Hansjurgens fails in curing any deficiencies of EP 1,219,278, Tamarkin, Castel, and Ella.

Moreover, Applicant submits that Hansjurgens does not provide any specific motivation or suggestion to a skilled artisan to make a combination of all the cited references for the purpose to arrive at the present invention. As Hansjurgens fails in teaching the use of the ultrasound apparatus, it is indeed impossible for a skilled artisan to be motivated and arrive at the present invention which requires the specific correlation of the operational frequencies of the ultrasound apparatus and the electrical stimulation apparatus. Thus, even *assuming* that a skilled artisan were to make a combination of all the cited references, he/she would still fail in the attempt as the combination still fails in teaching or suggesting each and every element of the claimed subject matter, as above mentioned.

Accordingly, Applicant submits that pending claims 33, 34, 74, and 75 are patentable over EP 1,219,278 and Tamarkin in view of Castel and Ella, and further in view of Hansjurgens. Therefore, reconsideration and withdrawal of the instant rejection under 35 USC 103(a) is proper and the same is requested.

In addition, claims 39, 81, and 82 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin and Castel, and further in view of Cosman. Applicant disagrees and hereby traverses the rejection.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin and Castel is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin and Castel.

Applicant contends that the addition of Cosman would not render the presently claimed subject matter obvious. Specifically, Cosman does not teach or suggest that varying the operational <u>frequency</u> of *the ultrasound apparatus* inversely proportional to the operational <u>frequency</u> of *the electrical stimulation apparatus* during a single treatment session (as required by this invention). Indeed, Cosman merely teaches devices for ultrasound imaging, and nothing more. Applicant thus submits that the addition of Cosman fails in making up for the deficiencies of EP 1,219,278, Tamarkin, and Castel.

Applicant also notes that Cosman does not provide any motivation or suggestion to a skilled artisan to combine and modify the teachings of all the cited references for the purpose to arrive at the present invention. Even *assuming* that a skilled artisan were to make such a combination, he/she would still fail in the attempt as the combination of these references still fails in teaching or suggesting each and every element of the claimed subject matter (e.g., the operational frequencies of the ultrasound apparatus and the electrical stimulation varied at the rates inversely proportional to each other during the same treatment session).

Accordingly, Applicant submits that claims 39, 81, and 82 are patentable over EP 1,219,278, in view of Tamarkin and Castel, and further in view of Cosman. Therefore, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

Still further, claims 41, 42, and 84 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over EP 1,219,278 in view of Tamarkin and Castel, and further in view of Lia. Applicant respectfully disagrees and hereby traverses the rejection.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin and Castel is also applicable in this section, and is incorporated herein by its entirety.

Applicant contends that the addition of Lia still fails in rendering the presently claimed subject matter obvious. Specifically, Lia does not teach or suggest an ultrasound apparatus with an operational intensity being 1.5 to 3 W/cm<sup>2</sup>. Lia does not teach or suggest varying the operational <u>frequency</u> of *the ultrasound apparatus* inversely proportional to the operational <u>frequency</u> of *the electrical stimulation apparatus* during a single treatment session (as required by this invention). Moreover, Lia does not present any specific motivation or suggestion to a skilled artisan to make a combination and a modification of the cited references for the purpose to arrive at this invention.

At least in view of the foregoing reasons, Applicant submits that claims 41, 42, and 84 are patentable over EP 1,219,278, in view of Tamarkin and Castel, and further in view of Lia. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

## **CONCLUSIONS**

In view of the foregoing, Applicant submits that all the pending claims of this application are allowable. Applicant respectfully requests entry of this Amendment and Response, reconsideration, and early favorable action by the Examiner. The Examiner is cordially invited to contact Applicant's undersigned representative at the number listed below to discuss any outstanding issues. Applicant thanks the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 04-1105, under the Order No. 64030(303625)

Respectfully submitted,

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